PD-L1 assays: An update on FDA-approvals and uses with companion immunotherapies

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Novel immunotherapies have recently demonstrated significant objective responses in many advanced malignancies. The standard therapy of some of these cancers had remained unchanged for decades despite poor outcomes. Immune checkpoint inhibitors, in particular those for the programmed cell death protein (PD-1) pathway, have bought great progress for the care of these patients in the past decade. Currently, the most clinically significant ligand of PD-1 is the programmed cell death ligand-1 (PD-L1). When this pair binds, cytotoxic T cell function is inhibited. Many types of tumors can express PD-L1 as a mechanism to evade the anti-tumor response of the immune system. By the end of 2016, the United States Food and Drug Administration (FDA) had approved four different immune checkpoint inhibitors for use in a total of six different types of malignancies. Many of these drug-indication combinations have an FDA-approved companion PD-L1 immunohistochemistry assay available. These PD-L1 assays are used to predict therapeutic responses and in some cases tumor PD-L1 positivity is a prerequisite for initiating therapy. Each of these assays uses a different anti-PD-L1 clone. The use of these antibodies and the interpretation of tumor PD-L1 expression are continually evolving, as well as the understanding of the overall impact of this information. Knowledge of the current state of these rapidly evolving drugs and assays will prepare researchers, manufacturers and clinicians for future applications of these promising antibodies.

Biography

Steven Alexander Mann received his Medical degree in 2015 from the University of Alabama, School of Medicine and is currently a Pathology Resident at the Indiana University School of Medicine. He is actively involved in managing molecular requests for his current institution and is a Member of the College of American Pathologists Engaged Leaders Network. He has multiple peer-reviewed publications on a variety of topics including a recent review of PD-L1 immunohistochemistry for genitourinary tumors and a chapter on biomarkers for hepatic and pancreaticobiliary malignancies.

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